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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,977	06/14/2007	Mark Ashby	1001.2219102	1136

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SEAGER, TUFTE & WICKHEM, LLC
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EXAMINER

MASHACK, MARK F

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,977	Applicant(s) ASHBY ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27,29-33,40-49,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,27,61 and 62 is/are allowed.
- 6) ☒ Claim(s) 40-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 6/15/2010. Claims 1, 27, 29-33, 40-49, and 61-62 are pending. Claims 29-33 have been withdrawn.

Allowable Subject Matter

1. Claims 1, 27, 61-62 allowed.

Response to Arguments

2. Applicant's arguments filed 6/15/2010 have been fully considered but they are not persuasive. Applicant argues that element **78** does not couple "the flexible disk to the hemostatic body". Examiner disagrees. The term "couple" is a very broad term and element 78 extends between the two elements so that it physically joins the two components in a spaced apart configuration. Additionally, as discussed below, the suture **34** also reads on the claimed limitations.

Specification

3. The abstract of the disclosure is objected to because it does not support an embodiment comprising "a connector disposed between the flexible disk and the hemostatic body" along with the Claim limitations of **Claims 42, 44-49**. Correction is required. See MPEP § 608.01(b).

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, “a connector disposed between the flexible disk and the hemostatic body” along with the Claim limitations of **Claims 42, 44-49** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 42, 44-49** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Claim 40** appears to be directed to the embodiment of Fig 8C since none of the other embodiments comprise "a connector disposed between the flexible disk and the hemostatic body". **Regarding Claim 42**, the connector appears to be part of the release mechanism, so it is not supported to have an additional release mechanism. **Regarding Claim 44, 46-49**, "the resilient extension member" is cited in a different embodiment of the specification. **Regarding Claim 45**, no suture is depicted in the claimed embodiment.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 40-42, 44-45** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al. ("Nash" US 5,700,277)** in view of **Hannam et al. ("Hannam" US 5,649,959)**.

Regarding Claim 40, **Nash** discloses an apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner pressure is greater than the outer lumen pressure, the apparatus comprising:

a flexible plug **32** having a center, top surface, and a bottom surface;

a hemostatic material to seal the blood vessel puncture site (Column 2, Lines 1-4); and

a connector (elements **34 or 36 or 78**) disposed between the disk and the hemostatic body, the connector positioned within a wall of the blood vessel puncture site (Fig 6, 9).

Nash discloses all of the claimed limitations except for the plug being sized to circumferentially cover the blood vessel puncture site and being sufficiently flexible to conform to and seal the blood vessel puncture site. However, **Hannam** teaches of a

similar apparatus comprising a plug with those properties (Column 7, Lines 34-46). It would have been obvious to modify the anchor with these properties in order to prevent injury to the vessel and prevent the release of the hemostatic vessel into the vessel.

Regarding Claim 41, the connector (**34, 36, 78**) has a smaller diameter than the flexible disk diameter and the hemostatic body diameter (Fig 9). **Regarding Claim 42, 44**, the apparatus further comprises a release mechanism comprising a resilient extension member **36** having an aperture at the top **62** a suture **34** which is secured to the hemostatic body **30** with knot **58**. An adhesive is an obvious variant of a knot. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element for another to yield predictable results. If that is not convincing, it was well known in the art at the time of the invention to reinforce a knot with an adhesive. **Regarding Claim 45**, the apparatus further comprising a suture **34** looped through the aperture.

10. **Claims 46-49** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash** in view of **Hannam** as applied to claim 1 above, and further in view of **Kensey et al.** (“**Kensey**” US 5,531,759).

Nash in view of **Hannam** disclose all of the claimed limitations except for the resilient extension member being made of hemostatic material and being encapsulated. However, **Kensey** teaches of thea similar resilient extension member **40** comprising a hemostatic agent (Column 13, Lines 43-49, and Column 9, Lines 25-33). The outer

periphery of the resilient extension member is considered a "dissolvable capsule" and the center would comprise a hemostatic material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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